MAR 1 8 2013

510(k) Summary

Contact Details

Applicant Name: Acumed LLC
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Kara Budor, Regulatory Specialist
503-207-1412

Date Prepared: December 17, 2012

Device Name

Trade Name: Acumed Cannulated Screw System

Common Name: Cannulated Screw

Classification: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener.

Class: II

Product Code: HWC, OUR

Legally Marketed Predicate Device(s)

There are six predicate devices. The comparison is to the Synthes 6.5 mm Cannulated Screw, the Synthes 7.0/7.3 mm Cannulated Screws, the aap Cannulated Screw, the Osteonics Osteo 4.0mm Cannulated Screw System, the Instratek Mini Cannulated Titanium Headed and Headless Screw Set, and the Pioneer Cannulated Screw System.

510(k) Number	Product Code	Trade Name	Applicant
K021932	HWC, OUR 888.3040	Synthes 6.5 mm Cannulated Screw	Synthes (USA)
K962011	HWC 888.3040	Synthes 7.0/7.3 mm Cannulated Screws	Synthes (USA)
K111316	HWC 888.3040	aap Cannulated Screw	aap Implantate AG
K983165	HWC 888.3040	Osteo 4.0mm Cannulated Screw System	Osteonics Corporation
K120493	HWC 888.3040	Mini Cannulated Titanium Headed and Headless Screw Set	Instratek, Inc.
K102903	HWC, OUR 888.3040	Pioneer Cannulated Screw System	Pioneer Surgical Technology

Device Description

The Acumed Cannulated Screw System consists of screws, washers, and accessories used for fixation of fracture, fusion and osteotomies of large and small bones appropriate for the size of the device.

Screws are available in a variety of diameters and lengths to accommodate various indications and patient anatomy. All screws and washers are made of titanium alloy per ASTM F136. Screws range in diameter from 3.0mm to 7.3mm and in lengths from 8mm to 150mm.

All implants are provided sterile and non-sterile.

Intended Use/Indications for use

The Acumed Cannulated Screw System consists of screws, washers, and accessories and is generally intended for fixation of fracture, fusion and osteotomies of large and small bones appropriate for size of device, which may include the following: Minimally invasive reconstruction of fractures and joints; Adjuvant for osteosynthesis in complex joint fractures; Multifragment joint fractures; Simple metaphyseal fractures; Fractures of the wrist, ankle, elbow, and shoulder; Condylar fractures; Epiphyseal and metaphyseal fractures in children; Osteochrondritis dissecans; Ostero-Chondral Fractures; Ligament avulsion injuries; Ligament fixation; Other small fragment, cancellous bone fractures; Small joint fusion; Areas where accurate screw placement is vital; Metatarsal and phalangeal osteotomies; Fractures of the tarsals, metatarsals and other fractures of the foot; Avulsion fractures and fractures of metatarsal V; Tarso-metatarsal and metatarso-phalangeal arthrodesis; Tarsal Fusions; Calcaneal and talar fractures; Subtalar arthrodesis; Ankle arthrodesis; Fractures of small joints, such as: Ankle fractures, Navicular fractures; Fractures of the fibula, malleolus, and calcaneus; Distal tibia and pilon fractures; Acetabular fractures; Other fractures of the pelvic ring; Sacroiliac joint disruptions; Fractures of the femoral head and neck; Supracondylar femoral fractures; Slipped capital femoral epiphyses; An adjunct to DHS in basilar neck fractures; Pediatric femoral neck fractures; Intercondylar femur fractures; Intracapsular fractures of the hip; Fractures of the distal femur and proximal tibia; Patellar fractures; Tibial plateau fractures; Small fragments of the hand and wrist; Fractures of the carpals and metacarpals; Carpal and metacarpal arthrodesis; Scaphoid fracture and other fractures of the hand; Phalangeal and interphalangeal fractures; Fractures of the ulna and radius; Radial head fractures; Fractures of the olecranon and distal humerus; Humeral head fractures; Ligament fixation at the proximal humerus; and Glenoid fractures. Washers may be used with the screws in certain applications.

Substantial Equivalence Comparison

The basic comparison between the Acumed Cannulated Screw System and the predicate devices is given in the table below.

Predicate	Material	Diameter	Length	Cannulated	Provided sterile / non-sterile
Acumed Cannulated Screw System	Titanium alloy per ASTM F136	3.0mm to 7.3mm	8mm to 150mm	Yes	Sterile and non-sterile
Synthes 6.5mm Cannulated Screw	SS and Ti alloy	6.5mm	20mm to 200mm	Yes	Unknown
Synthes 7.0/7.3mm Cannulated Screws	SS and Ti alloy	7.0mm to 7.3mm	Unknown	Yes	Sterile
aap Cannulated Screw	Ti alloy per ASTM F136 or ISO 5832-2 SS per ASTM F138 or ISO 5832-1	2.7mm to 7.5mm	Unknown	Yes	Unknown
Osteonics Corporation Osteo 4.0mm Cannulated Screw System	Titanium 6Al-4V ELI alloy	4.0mm	Unknown	Yes	Sterile and non-sterile
Instratek Mini Cannulated Titanium Headed and Headless Screw Set	Titanium alloy (Ti6AL4V)	2.5mm to 4.0mm	Unknown	Yes	Unknown
Pioneer Cannulated Screw System	Biodur 108 per ASTM F2229	3.5mm to 7.5mm	8mm to 200mm	Yes	Sterile and non-sterile

The Acumed Cannulated Screw System, the Synthes 6.5 mm Cannulated Screw, the Synthes 7.0/7.3 mm Cannulated Screws, the aap Cannulated Screw, the Osteonics Osteo 4.0mm Cannulated Screw System, the Instratek Mini Cannulated Titanium Headed and Headless Screw Set, and the Pioneer Cannulated Screw System are all sets of cannulated screws which are used to achieve fixation. There are some differences, but none of them raise new issues of safety or effectiveness. The Acumed Cannulated Screw System is substantially equivalent to the predicate devices.

Non-clinical Testing

The non-clinical testing included in this submission includes testing to ASTM F543.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 18, 2013

Acumed LLC
% Ms. Kara Budor
Regulatory Specialist
5885 Northwest Cornelius Pass Road
Hillsboro, Oregon 97124

Re: K123890
Trade/Device Name: Acumed Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, OUR
Dated: December 17, 2012
Received: December 18, 2012

Dear Ms. Budor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123890 (pg 1/1)

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices